May 21, 2003

Connie L. Deford
Global Environment, Health & Safety Manager
The Dow Chemical Company
1691 North Swede
Midland, MI 48674

Dear Ms. Deford:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Diphenyl Oxide posted on the ChemRTK HPV Challenge Program Web site on January 22, 2003. I commend Solutia, Inc and The Dow Chemical Company for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Solutia, Inc and The Dow Chemical Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

*-S-*

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: A. Abramson
W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:**
**Diphenyl Oxide**

## Summary of EPA Comments

The sponsors, Solutia, Inc. and the Dow Chemical Company, submitted a test plan and robust summaries to EPA for Diphenyl Oxide (CAS No. 101-84-8) dated December 27, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 22, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

2. Environmental Fate. Adequate data are available for photodegradation, stability in water, and fugacity. Testing needs to be conducted for biodegradation.

3. Health Effects. All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program. The submitter needs to add information to the robust summaries.

4. Ecological Effects. EPA reserves judgment on the adequacy of the submitted toxicity data on fish, daphnia, and green algae, pending addition of critical information on exposure conditions to the robust summaries.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

## EPA Comments on the Diphenyl Oxide Challenge Submission

### Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

EPA agrees that adequate data are available for these endpoints.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA agrees that adequate data are available for photodegradation, stability in water, and fugacity.

*Biodegradation*. The inherent biodegradation study provided for this endpoint does not appear to discuss mechanisms of loss of the test material (biodegradation versus volatilization or sorption to sludge inoculum) and is not a ready biodegradation test. For the purposes of the HPV Challenge Program, the submitter needs to provide ready biodegradation data following OECD TG 301.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

*Reproductive/developmental toxicity.* Testing was conducted on commercial grade diphenyl oxide, presumed to be 98% pure, in the 90-day repeated-dose test (used to address reproductive effects) and on a mixture of 73.5% diphenyl oxide and 26.5% biphenyl for the developmental study. Although the submission did not address the possible contributions of biphenyl to reproductive/developmental outcomes, published data (Khera, et al) indicate that biphenyl is not likely to contribute significantly to the results seen for the developmental/reproductive endpoint. Diphenyl oxide causes maternal toxicity at lower levels than does biphenyl.

Ecological Effects (fish, invertebrates, and algae).

The estimated Henry's Law Constant of $2.8 \times 10^{-4}$ atm-$m^3$/mole suggests that diphenyl oxide may volatilize during testing. Therefore, EPA defers judgment on the adequacy of these studies pending receipt of more detailed information on whether test chemical concentrations were nominal or measured.

**Specific Comments on the Robust Summaries**

Environmental Fate and Transport

*Stability in Water*. The study summary should state that the chemical lacks hydrolysable functional groups.

Health Effects

The purity of the test substance was not properly described for some of the studies.

Ecological Effects

The studies submitted did not indicate the exposure conditions used. The robust summaries should indicate whether test concentrations were nominal or measured.

**Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

**References**

Khera et al. 1979. Assessment of the Teratogenic Potential of Piperonyl Butoxide, Biphenyl, and Phosalone in the Rat. Toxicology and Applied Pharmacology 47, 353-358, 1979.